CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone):

PROTOCOL TITLE:

ABBREVIATED TITLE (30 characters or less):

PROPOSED START DATE: _____ END DATE: _____ TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): _____

COLLABORATING INSTITUTE INFORMATION:
Will subjects participate on the protocol at the NIH CC? ☐ Yes ☐ No
Will subjects participate on the protocol at other sites? ☐ Yes ☐ No
If yes, are the sites ☐ Domestic ☐ Foreign ☐ Both
Is NIH the coordinating site?
☐ Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☐ No. Coordinating Site is_____

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None ☐ Asian
☐ Male ☐ Black or African American
☐ Female ☐ White
☐ Children <18 ☐ Hispanic or Latino
☐ American Indian/ Alaskan Native ☐ Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:
Minimum Age Permitted _____
Maximum Age Permitted_____
Pediatric ☐ None ☐ <1 Yr. ☐ 1-6 Yrs. ☐ 7-17 Yrs.
Protocol involves healthy volunteers? ☐ Yes ☐ No
Are Healthy Volunteers NIH Employees? ☐ Yes ☐ No
Subject Remuneration? ☐ Yes ☐ No
Does the protocol permit self referral? ☐ Yes ☐ No

NOTE: The protocol shall include a discussion of the rationale for subject selection/exclusion, including gender and ethnicity of the population at risk, as well as recruitment plans and procedures.

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History – Disease Progression
☐ Natural History – Sample/Data Collection or Analysis
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? ☐ Yes ☐ No

KEY WORDS (Enter words, not contained in the title, describing the protocol)
1. _____
2. _____
3. _____
4. _____
5. _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.):
☐ None ☐ Medically indicated ☐ Research indicated*
*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE
FDA No. _____.
IND/IDE Name: _____.
Sponsor: _____.
Who is the manufacturer of the above entity: _____
_____

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☐ Yes (Append a statement of disclosure)
☐ No

Has the NIH IRP COI Guide been distributed to Non-NIH Investigators? ☐ Yes ☐ No
Based on the criteria at their institution, has a conflict been reported?
☐ Yes. Describe in attached narrative. ☐ No

CONFLICTS OF INTEREST REVIEW:

Date submitted to IC DEC:_____ Date cleared by IC DEC:_____

MEDICAL ADVISORY INVESTIGATOR (if necessary) Initial (Name, Inst/Branch, Telephone, Address, Email and indicate if an NIH employee):
_____.

LEAD ASSOCIATE INVESTIGATOR – Initial (Name, Inst/Branch, Telephone, Address, and indicate if an NIH employee):
_____.

RESEARCH CONTACT: Initial (Name, Inst/Branch, Telephone, Address, Email and indicate if an NIH employee):
_____.

ASSOCIATE INVESTIGATOR(S): Initial (Name, Institute/Branch, Telephone, Address and indicate if an NIH employee)
1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE	Principal Investigator	Print/Type Name	Date		Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	Print/Type Name	Date		Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Br. Chief/CC Dept. Head of Acct. Invest.	Print/Type Name	Date		Send to Institute/Center Scientific Review Committee
APPROVALS	For Institute/Center Scientific Review Comm.	Print/Type Name	Date		Send to Clinical Director
	Clinical Director	Print/Type Name	Date		Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Print/Type Name	Date	Protocol & Consent Approval Completed	Send to Office of Protocol Services, through IRB Protocol Coordinator
PATIENT SAFETY/ RESOURCE REVIEW	Director, Clinical Center	Print/Type Name	Date		Return to Office of Protocol Services, (10/1S231B)
COMPLETION	Protocol Specialist	Date	**PROTOCOL NO.**		

The following data elements are required by the National Library of Medicine for posting on clintrials.gov and meets the registration requirements set forth by the International Committee of Medical Journal Editors (ICMJE) for publishing. http://www.clinicaltrials.gov/

CONDITIONS: Select up to 5 primary diseases or conditions being studied, using NLM Medical Subject Heading (MeSH) controlled vocabulary. The conditions are used to index studies. http://www.nlm.nih.gov/mesh/MBRowser.html

1. _____ 4. _____
2. _____ 5. _____
3. _____

STUDY TYPE: Nature of the investigation. Select Interventional or Observational, in addition to the most appropriate term describing the protocol for each of the corresponding categories.

☐ **Interventional Studies**	☐ **Observational Studies**
Purpose: Reason for the protocol ☐ Treatment ☐ Prevention ☐ Diagnosis ☐ Educate/Train	Purpose: reason for the protocol ☐ Natural History ☐ Screening ☐ Psychosocial
Study Design: participant selection ☐ Randomized Trial ☐ Non-randomized Trial	Duration of Sampling: protocol sample in ☐ Longitudinal ☐ Cross-sectional
Masking: knowledge of intervention ☐ Open ☐ Single Blind ☐ Double Blind	Selection Method: sample selection ☐ Targeted Population ☐ Random Sample ☐ Case Control
Control: nature of the interventional control ☐ Placebo ☐ Active ☐ Uncontrolled ☐ Historical ☐ Dose Comparison	Timing: data collection period ☐ Retrospective ☐ Prospective ☐ Both
Assignment: intervention groups ☐ Single Group ☐ Parallel ☐ Cross-over ☐ Factorial ☐ Expanded Access	
Endpoint: primary outcome that the protocol is designed to evaluate ☐ Safety ☐ Efficacy ☐ Safety/Efficacy ☐ Bio-equivalence ☐ Bio-availability ☐ Pharmacokinetics ☐ Pharmacodynamics ☐ Pharmacokinetics/pharmacodynamics	

COMPLETE FOR INTERVENTIONAL STUDIES ONLY

INTERVENTIONS: Provide up to 10 primary interventions identifying a category for each. Category selections are: Drug, Gene Transfer, Vaccine, Behavior, Device, and Procedure.

	Category	Intervention		Category	Intervention
	Ex. Drug	AZT		Ex. Behavior	Hypnosis
1.			6.		
2.			7.		
3.			8.		
4.			9.		
5.			10.		

OUTCOME MEASURE(S)/ENDPOINT(S): Examples – changes in cardiac output, changes in cognitive function, changes in drug or antibody.

Primary: main outcome representing a primary study question(s). _____

Secondary: outcome(s) of interest to a study, but not representing the primary study question(s). _____